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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jacob N. Wohlstadter

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06/14/2005

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,796	WOHLSTADTER ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-126 and 135-176 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-126 and 135-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 3/23/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-109, 127-134 and 177 are cancelled.
2. Currently, claims 110-126 and 135-176 are under examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 110-114, 118-121, 135-145, 155-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weetall et al. in view of Forrest et al. (US 5149630).

Weetall et al. teach a sensor for detecting analytes in test sample. Weetall et al. teach placing the samples in a plurality of wells, e.g. multi-well plate, where each well contains

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independently addressable working electrodes (component 22) and counter electrode (component 24) in each well (See Figure 1 and 2; Col. 2, line 42-55). Weetall et al. also teach immobilizing antibodies (T₄ antibodies) on the particles and place adjacent to the working electrodes to detect analyte (See Example 1 and claim 1-3). However, Weetall et al. do not explicitly teach immobilizing antibodies directly on the electrodes for detection purpose.

Forrest et al. teach the advantages of direct immobilization of antibodies on the working electrode. Forrest et al. teach that direct immobilization of the antibodies for detection the analyte can improve sensitivity and efficiency (Col. 8, line 48-68).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Weetall et al. to use direct immobilization of antibodies on the working electrode as taught by Forrest et al. to increase the sensitivity and efficiency of the assay.

With respect to claims 111-114, 138-145, Weetall et al. teach using a non-conductive layer (component 40) as a mask having plurality of holes sealed against the said electrode (See Figure 1, Col. 2, line 40-55). The composition of the electrode is of graphite, i.e. carbon (Col. 2, line 37-40).

With respect to claims 118-121, 155-161, 166-171, Weetall teach placing one counter electrode in each well in the multi-well plate and electrically connect to each other (See Figure 1-3). Forrest et al. teach using electrochemiluminescent label for detection of analyte (See example 2 and 3).

With respect to claims 162-165, the device of Weetall et al. contains 12 multi-wells for detecting test samples (See Figure 3 and Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have increase the size for detecting more samples, e.g. from 12 multi-wells to 24 multi-wells, since it has

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been held mere duplication of the essential working parts of a device or change in the size of a component involves only routine skill in the art, and it is within ordinary practice for detection more samples efficiently by increasing detection capacity. See *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 and *In re Rose*, 105 USPQ 237.

4. Claims 115-116, 146-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weetall et al. in view of Forrest et al., and further in view of Rourke et al. (US 4720910).

Both Weetall and Forrest et al. references have been discussed but are silent in use of the composite materials for electrode including a polymeric material and carbon particles.

Rourke et al. teach a method of efficient utilization of electrode. Rourke et al. teach using a composite comprising the electrode material, a polymeric electrolyte, and an electronically conducting medium such as graphite, e.g. carbon particle (Col. 1, line 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Weetall and Forrest et al. with the composite material for the electrodes as taught by Rourke et al. since it is well-known in the art to increase electrode utilization efficiency by the composite materials.

5. Claims 117, 124-126, 152-154 and 174-176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weetall et al. in view of Forrest et al., and further in view of Heller et al. (US 5605662).

Both Weetall and Forrest et al. references have been discussed but are silent in teach the size of electrodes and using light detector for detecting electrochemiluminescence signals.

Heller et al. disclose a device to concentrate analytes for DNA hybridization. The apparatus comprising a plurality of wells containing electrodes (See component 62 in Figure 6). Heller et al. teach that the diameter for the electrode holes is around 1 mm

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(Col. 14, line 45-49). It would have been an obvious matter of design choice to have the smaller size of electrodes, such as taught by Heller et al., to incorporate into Weetall and Forrest et al. device, since such a modification would involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237.

Heller et al. teach using fluorescence dye, ethidium bromide (EB) for detecting analyte using electrodes by change electrochemiluminescence signals. The signal change can be detected and recorded by a light detector (Col. 25, line 54-60; Col. 27, line 1-28).

Therefore it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Weetall and Forrest et al. with the method of using fluorescence signals detected by light detector to measure the amount of analytes in the sample since the art is analogous, e.g. electrochemical analysis, and it is well-known in the art to measure fluorescence change in identify analytes.

1. Claims 122-123 and 172-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weetall et al. in view of Forrest et al., and further in view of Siddigi et al. (US 554113).

Weetall and Forrest et al. references have been discussed but are silent in teaching use of metal-containing organic compound for electrochemiluminescent label.

Siddigi et al. teach using an electrochemiluminescent method for detecting an analyte in an aqueous solution by using organometallic complexes, including ruthenium, osmium, rhodium for the benefits of maintaining thermal, chemical and photochemical stability, high and long emission lifetimes (Col. 2, line 27-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Weetall and Forrest et al. with the an alternative chemiluminescence methodologies as taught by Siddigi et al. because the organometallic

compounds are well-known in the art for maintaining thermal, chemical stability as well as achieving high and long emission lifetimes.

Response to Applicant's Arguments

2. Applicant's arguments with respect to claims 110-126 and 135-176 have been considered but are moot in view of the new ground(s) of rejection.

Weetall et al. reference

3. Applicant argues that the newly amended feature, i.e. "antibodies immobilized on" independent addressable electrodes, is distinguishable from the reference of Weetall et al because Weetall et al. merely teach immobilized antibodies on particles placing adjacent to the working electrodes (See Remarks, page 11-12). Examiner agrees the added feature overcome the 35 USC 102 (b) rejections as set forth in the previous Office Action, nevertheless immobilizing antibodies are known in the art for detection analytes, especially in the field using electrodes as detection means. The amended claims are still considered obvious under the combined references of Weetall et al. in view of Forrest et al.

Applicant also argues that the current invention has a "multi-well" feature, whereas as the reference of Weetall et al. does not contain this feature (See Remarks, page 12, last paragraph). Examiner would like to point out the claim language recited by applicant does not specify this feature, i.e. claim 110. The Weetall et al. reference is a plate containing 12 "multi-wells" having independent addressable electrodes.

Rourke et al. reference

4. Applicant argues that Rourke et al. merely teach the use of composite materials in electrochemical cells, consequently the disclosure of Rourke et al. does not provide one artisan in

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the art with a reasonable expectation of success in immobilizing antibodies on the composite electrode. Applicant's argument has been considered but is not persuasive.

The newly 35 USC103 (a) rejections under Weetall et al. in view of Forrest et al. have provided the motivation to immobilize antibody on the electrodes as detailing in this Office Action. The option of using different materials for optimal results has been held within ordinary skill in the art. See In re Aller, 105 USPQ 233 and In re Boesch, 617 F.2d 272. Therefore, it would have been involved a routine practice in the art to use electrodes comprising composite materials to immobilize antibodies since the Forrest et al. had provided motivation to immobilize antibodies on the electrode for better efficiency, e.g. sensitivity and it is well-known in the art to coat the electrode with composite carbon materials for detection ion/current change.

Heller et al. reference

The anticipation rejection under 102 (e) has been withdrawn by the examiner in this Office Action. However, the feature of using light detector to detect electrochemiluminescence signal is well-known in the art and often used in the electrochemistry field as discussed in this Office Action.

Conclusion

5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner



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June 1, 2005



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06/10/05